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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jan Weber	Confirmation No.	6210
Serial No.:	10/084,857	Examiner:	Vy Q. Bui
Filed:	February 25, 2002	Art Unit:	3734
		Docket:	01-264US

Title: NON-INVASIVE HEATING OF IMPLANTED VASCULAR TREATMENT DEVICE

MS APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items and information (as indicated with an "X"):

X Return postcard

X Appellant's Reply Brief to Examiner's Supplemental Answer dated October 17, 2006 (27 pgs.)

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Respectfully Submitted,
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Nov. 17, 2006
Date:

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Docket No.: 01-264US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Jan Weber

Application No.: 10/084,857 Confirmation No: 6210

Filed: February 25, 2002 Art Unit: 3734

For: Non-Invasive Heating of Implanted Vascular Treatment Device

Examiner: Vy Q. Bui

APPELLANT'S REPLY BRIEF TO EXAMINER'S SUPPLEMENTAL ANSWER DATED OCTOBER 17, 2006

MS Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief, in compliance with 37 C.F.R. § 41.41, is in response to the Examiner's Supplemental Answer dated October 17, 2006 and in furtherance of the Reply Brief filed July 6, 2006, Appellants' Brief filed March 22, 2006 and Notice of Appeal filed under 37 C.F.R. § 41.31 on February 22, 2006.

The Examiner's Grounds for Rejection are substantially the same as those presented in the Final Office Action dated November 23, 2005. Appellant has addressed these rejections in their Appeal Brief dated March 22, 2006 and Reply Brief dated July 6, 2006. In the Examiner's Supplemental Answer dated October 17, 2006 the Examiner provides a response to the arguments presented in the Reply Brief. Appellant respectfully traverses the assertions and conclusions provided in the Examiner's Reply Brief and the Examiner's Supplemental Answer. The following is the Appellant's Reply Brief to the Examiner's Supplemental Answer.

This Reply Brief contains items under the following headings as required by 37 C.F.R. § 41.37:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of Claimed Subject Matter
VI. Grounds of Rejection to be Reviewed on Appeal
VII. Argument – Reply to Examiner's Supplemental Answer
VIII. Claims Appendix
IX. Evidence Appendix
X. Related Proceedings Appendix

The final page of this brief bears the attorney's signature.

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is SciMed Life Systems, Inc. a corporation established under the laws of the State of Minnesota and having a principle place of business at One Scimed Place, Maple Grove, Minnesota 55311.

II. RELATED APPEALS AND INTERFERANCES

Appellant is unaware of any related appeal or interference.

III. STATUS OF CLAIMS

The Claims 1-2, 4-33 and 42-49 are pending. Claims 3 and 34-41 are cancelled. Claims 9, 10, 13-19, 27 and 30-33 are withdrawn. No claims are allowed. Claims 1, 2, 4-8, 11, 12, 20-26, 28, 29 and 42-49 stand rejected and are the subject of this appeal and the following response to the Examiner's Answer.

IV. STATUS OF AMENDMENTS

Appellant filed a Response after Final Rejection on January 4, 2006 (hereinafter "Final Response") with no claims amended, added, or cancelled. The Examiner responded to the Final Response with an Advisory Action mailed January 31, 2006. Appellant filed an Appeal Brief on March 22, 2006 with no claims amended, added or cancelled. This Reply Brief is in response to the Examiner's Answer to Appeal Brief dated June 15, 2006 with no claims amended, added or cancelled.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a vascular treatment device. The device includes a stent formed with a magnetically susceptible material having a magnetic susceptibility that decreases within a preselected temperature range (page 5, lines 15-17; page 6, lines 5-16; Figure 1, element 12).

Dependent claim 2 to independent claim 1 recites that the susceptible material has a Curie temperature in the preselected temperature range (page 6, lines 5-16).

Dependent claim 4 to independent claim 1 recites that the stent includes a core, such that the susceptible material includes a coating on a surface of the core (page 8, lines 1-5 and lines 16-17).

Dependent claim 5 to dependent claim 4 recites that the coating is disposed on an external surface of the core (page 8, lines 5-7; Figure 2, element 12).

Dependent claim 6 to dependent claim 4 recites that the coating is disposed on an internal surface of the core (page 8, lines 7-9; Figure 3, element 12).

Dependent claim 7 to dependent claim 4 recites that the coating is disposed on both an internal and external surface of the core (page 8, lines 10-13; Figure 4, element 12).

Dependent claim 8 to independent claim 1 recites that the stent includes a core, such that the core is formed of the susceptible material (page 8, lines 22-24).

Dependent claim 11 to dependent claim 4 recites that the core comprises a magnetically susceptible material (page 9, lines 9-12).

Dependent claim 12 to independent claim 1 recites that the susceptible material comprises one of Ferrite Oxide (FEO) (page 6, lines 16-17) and Chromium Oxide (CrO) (page 6, lines 21-25).

In an additional embodiment, independent claim 20 recites a vascular treatment system that includes an electromagnetic field generator (page 5, lines 17-19; Figure 1, element 18). The system also includes a medical device (page 5, lines 14-16) deliverable to a treatment site (page 5, lines 14-17). The medical device includes a magnetically susceptible material being magnetically susceptible to an electromagnetic field generated by the generator and having a Curie temperature in a preselected range (page 5, lines 24-30; page 6, lines 1-20), such that the implantable device heats to a temperature sufficient to treat the treatment site when the electromagnetic field is applied (page 7, lines 21-25).

Dependent claim 21 to independent claim 20 recites that the medical device comprises a stent having a core material (page 8, lines 16-18).

Dependent claim 22 to dependent claim 21 recites that the susceptible material comprises a coating on a surface of the core material (page 8, lines 1-5).

Dependent claim 23 to dependent claim 22 recites that the coating is disposed on an external surface of the core material (page 8, lines 5-7; Figure 2, element 12).

Dependent claim 24 to dependent claim 22 recites that the coating is disposed on an internal surface of the core material (page 8, lines 7-9; Figure 3, element 12).

Dependent claim 25 to dependent claim 22 recites that the coating is disposed on both an internal and external surface of the core material (page 8, lines 10-13; Figure 4, element 12).

Dependent claim 26 to dependent claim 21 recites that the core material is formed of the susceptible material (page 8, lines 10-13; Figure 4, element 12).

Dependent claim 28 to dependent claim 22 recites that only preselected portions, less than the entire core, are coated with the susceptible material (page 11, lines 25-28).

Dependent claim 29 to dependent claim 22 recites that the core material comprises a magnetically susceptible material (page 9, lines 9-12).

Dependent claim 42 to independent claim 1 recites that the coating includes a polymer binder for the magnetically susceptible material (page 9, lines 9-12).

Dependent claim 43 to independent claim 1 recites that the core is a metal selected from the group stainless steel, Nitinol, and tantalum (page 8, lines 17-19; page 14, lines 7-8).

Dependent claim 44 to independent claim 1 recites that the coating includes a sintered coating of the magnetically susceptible material on the core (page 8, lines 1-5 and lines 16-17).

Dependent claim 45 to independent claim 1 recites that the coating includes a painted coating of the magnetically susceptible material on the core (page 8, lines 1-5 and lines 16-17).

Dependent claim 46 to independent claim 20 recites that the coating includes a polymer binder for the magnetically susceptible material (page 8, lines 13-16).

Dependent claim 47 to independent claim 20 recites that the core is a metal selected from the group stainless steel, Nitinol, and tantalum (page 8, lines 17-19; page 14, lines 7-8)

Dependent claim 48 to independent claim 20 recites that the coating includes a sintered coating of the magnetically susceptible material on the core (page 8, lines 1-5 and lines 16-17).

Dependent claim 49 to independent claim 20 recites that the coating includes a painted coating of the magnetically susceptible material on the core (page 8, lines 1-5 and lines 16-17).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The first issue is whether claims 1-2, 4-7, 20-25, 43 and 47 are unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,364,823 to Garibaldi et al. (hereinafter "Garibaldi").

The second issue is whether claims 8, 11-12, 26, 28-29, 42, 44-46 and 48-49 are unpatentable under 35 U.S.C. § 103(a) as obvious over Garibaldi.

VII. ARGUMENT

RESPONSE TO DETAILED ACTION

In the Examiner's Supplemental Answer dated October 17, 2006 it was asserted that the "applicant did not provide any argument regarding the rejections under 35 U.S.C. 103(a) after 'Non Final Rejection' (paper 5/16/2005) and after 'Final Rejection' (paper 11/23/2005). However, after 'Final Rejection', the applicant's Attorney has raised too many new arguments for the Board of Patent and Appeals and Interferences to consider."

Appellant respectfully submits that they are unaware of any rule or law pertaining to the number of arguments that can be raised in the Appeal Brief as filed by the Appellant. In addition, Appellant is unaware that new arguments are/were precluded from the Appeal Brief as filed on March 24, 2006. Appellant respectfully submits that they were being responsive to each and every ground of rejection stated

by the Examiner, as is allowed and required, lest the ground of rejection be summarily sustained by the Board of Patent and Appeals and Interferences. It is also the Appellant's understanding that any argument not included in the Appeal Brief and/or Reply Brief will be refused to be considered by the Board of Patent and Appeals and Interferences, unless good cause is shown. As such, Appellant included a complete response to each and every ground of rejection stated by the Examiner in their Appeal Brief, as is allowed.

Furthermore, Appellant respectfully submits that no new arguments were raised in Appellant's Reply Brief dated July 6, 2006. Rather, Appellant addressed the arguments raised by the Examiner in the Examiner's Answer dated June 15, 2006.

Appellant now presents a Reply Brief under 37 C.F.R. §41.41 in response to the Examiner's Supplemental Examiner's Answer dated October 17, 2006, as provided for by 37 C.F.R. §41.43(b).

REJECTIONS UNDER 35 U.S.C. §102(e)

Claims 1-2, 4-7, 20-25, 43 and 47 were rejected under 35 U.S.C. § 102(e) as being anticipated by Garibaldi. Appellant respectfully traverses the rejection of the claims, and addresses their rejection as follows.

Claim 1

In response to Appellant's arguments, the Examiner asserts that Garibaldi "teaches a stent formed by magnetic patches 120, which are made from a highly flexible material such as silicone or plyurethane [*sic*] or a bioadsorbalbe [*sic*] material (col. 7, line 65 to col. 8, line 2), which stent can be adsorbable overtime [*sic*] by the body (col. 8, lines, 59-61) and hoop 122 made of nitinol or some other structure or construction (col. 8, lines 6-9) and a magnetic responsive material (col. 8, lines 12-14)" (page 3 of Examiner's Supplemental Answer). Appellant respectfully traverses.

As discussed in Appellant's Appeal Brief and Reply Brief to Examiner's Answer, Garibaldi provides for using multiple magnetic patches for forming

continuous interior wall reinforcement, like a stent (col. 8, lines 53-61). To accomplish this, the "patch 120 includes magnetic material, for example, particles of a magnetically responsive material or magnetic wire mesh." Garibaldi indicates that food grade iron particles of about 0.5 microns to about 50 microns are a suitable magnetic material. Garibaldi also indicates that a magnetic field is applied so as to move the patch 120 (col. 8, lines 26-32).

The Examiner Supplemental Answer also asserts that Garibaldi teaches a stent including magnetic material for manipulation when the stent is deployed inside a patient body and that the magnetic material must have an associated Curie temperature (page 3 of Examiner's Supplemental Answer). Appellant respectfully traverses these assertions as applied to claim 1.

First, the Currie temperature for iron is about 770° C. As such, one skilled in the art would not use iron particles as the "magnetic material" provided by Garibaldi. For one reason, to decrease the magnetic susceptibility of the iron particles would require heating the stent to above the Curie temperature of 770° C. So, use of iron would not be suitable for a stent formed with a magnetically susceptible material having a magnetic susceptibility that decreases within a preselected temperature range, as recited in claim 1.

Second, while Garibaldi does identify magnetically controllable embolic materials, they are provided in a separate and unrelated section of Garibaldi that discusses a separate and distinct embodiment of the disclosure entitled "Embolic Compositions" (starting at col. 11, line 17). So, as previously discussed in Appellant's Appeal Brief and Reply Brief to Examiner's Answer, the Examiner appears to suggest that the magnetic material in the "flowable magnetic material" of the "Embolic Compositions" could be used for the "magnetic material" of the "patch 120." Using Garibaldi in this manner, however, results in a structure that would not work for its intended purpose. As such, Garibaldi is not a suitable document on which to base an anticipatory rejection of claim 1.

As provided for herein, Garibaldi does not expressly teach that the "magnetic material" in the "Embolic Compositions" can be, or should be, used with the "patch 120." So, even though Garibaldi may disclose the claimed elements in isolation

(much like a dictionary contains the words of a given novel), the reference does not expressly show the invention in as complete detail as is contained in claim 1.

One apparent reason for why Garibaldi does not expressly teach that the "magnetic material" in the "Embolic Compositions" can be, or should be, used with the "patch 120" is that the "patch 120" would no longer work as intended if the magnetic materials identified by the Examiner were used with the "patch 120." In other words, Garibaldi did not enable the embodiment of the "patch 120" suggested by the Examiner because such an embodiment is not functional.

In the section of Garibaldi entitled "Embolic Compositions," there is described a variety of what are called a "magnetically controllable embolic material" that can undergo a reduction in magnetic properties. As indicated by Garibaldi, this reduction in magnetic properties can occur due to a chemical transition of the magnetic particles (col. 12, lines 17-59), a decay process (col. 12, line 60 – col. 13, line 9), or with a magnetic material having a sufficiently high Curie temperature (col. 13, lines 10-32). In this later embodiment, the temperature of the patient is reduced below the magnetic material Curie temperature to allow it to remain magnetic. When the body temperature of the patient is restored Garibaldi indicates that the magnetic material loses its magnetic properties.

Specifically, Garibaldi states that:

> Magnetic material whose Curie temperature are below normal body temperature (98.6 F) can be used to make the embolic material magnetic. The surrounding tissue would be sub-cooled to a temperature below this point while the aneurysm is filled and polymerization is occurring so that the material is highly susceptible to the magnetic field. When the procedure is completed the patient would be allowed to warm up to normal body temperature and the filled aneurysm would lose its ferromagnetic properties. Examples of materials with appropriate Curie temperatures are Gadolinium (15 C) and PdNi alloy (32 C). Gadolinium is presently used in MRI contrast agents, and PdNi alloy is used as passively-regulated implants that can be heated using magnetic fields. (Col. 13, lines 20-33, emphasis added).

So, at body temperatures the magnetic material of the "Embolic Compositions" has no ferromagnetic properties. In other word, the magnetic material is no longer magnetic.

Garibaldi teaches that the "patches 120" used to form the "stent" are not only applied using a magnetic field, but also that it is done at body temperature (there is no teaching in Garibaldi of "cooling" or "sub-cooling" the blood vessel prior to applying the "patches 120"). So, the "magnetic materials" identified by the Examiner in Garibaldi to be used with the "patches 120" are not magnetic at body temperature. This is why Garibaldi does not, and cannot be used, to teach the embodiment suggested by the Examiner. In other words, Garibaldi does not teach what is suggested by the Examiner because such a structure will not work for its intended purpose.

If, however, the Examiner position is that the tissues in the area of the "patches 120" are sub-cooled, the patches 120 will once again not work. For example, as provided by Garibaldi, "[i]n the preferred embodiment, the patch 120 includes a hoop 122 of nitinol . . . that causes the patch 120 to open to its normal . . . shape" (col. 8, lines 2-7). Garibaldi also indicates that "other structure or construction can be provided to cause the patch to assume its extended configuration," but Garibaldi does not teach any other material besides nitinol that can be used to form the "hoop 122" (i.e., structure is defined as something made up of a number of parts that are held or put together in a particular way, and construction is defined as the way in which something is built or put together [The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000]). So it would appear that the "hoop 122" is only made of nitinol.

As one skilled in the art understands, nitinol is a metal that remembers its geometry. After it is deformed, it regains its original geometry by itself during heating or, at higher ambient temperatures, during unloading. Garibaldi indicates that the tissue surrounding the magnetic material having the sufficiently high Curie temperature needs to be sub-cooled so that the magnetic material can be highly susceptible to a magnetic field. However, sub-cooling the tissue in the area of the "patch 120" with this magnetic material runs counter to allowing the nitinol of "the

hoop 122" to obtain its predetermined shape. For example, once the patch 120 having this magnetic material was moved under the influence of the magnetic field, the patch 120 would then be warmed to allow the nitinol "hoop 122" to expand to its preconfigured shape. Upon warming, however, the nitinol of "the hoop 122" could move the patch 120 in unpredictable ways relative to its location within the body, negating any potential benefit of having used the magnetic material having the sufficiently high Curie temperature. This provides an additional reasonable explanation as to why both Garibaldi did not arrange the elements as recited in claim 1 and why one skilled in the art would not now arrange the elements recited in Garibaldi to provide the invention recited in claim 1.

Similarly, one skilled in the art would not reasonably understand that the "hoop 122" could first be expanded under normal body temperatures followed by a sub-cooling of the surrounding tissue in order to allow the magnetic material to move under the influence of the magnetic field. As will be appreciated, when implanting medical devices in the vasculature, every precaution must be taken to prevent the medical device from being released into and possibly occluding the blood vessel. Once released to allow the "hoop 122" to expand, the magnetic particles of the "patch 120" would not be useful in controlling the device as they would be above their Curie Point (i.e., no longer ferromagnetic). The Examiner would appear to concur with this point in the November 23, 2005 Final Office Action by asserting that "[n]otice that body temperature (98.6F) provides heat that would decrease magnetic property of stent formed with patches 120" (page 4). So, even if sub-cooling were to begin once the "hoop 122" was fully deployed, there would still likely be an unacceptable amount of time during which the "patch 120" would be outside the control of any applied magnetic forces.

Finally, Appellant respectfully notes that Garibaldi does not teach a "stent 120" as asserted by the Examiner. Rather, Garibaldi provides a "patch 120" that can be used to form a continuous interior wall reinforcement, like a stent. In addition, as discussed above, selecting the magnetic material from Garibaldi as suggested by the Examiner would lead to inoperative embodiments of the "patch 120." As discussed above, this is why Garibaldi cannot be reasonably be used to teach the identical

invention in as complete detail as is contained claim 1, and why it does not teach each and every claim element arranged as in claim 1. As such, Appellant respectfully submits that Garibaldi does not support a proper anticipation rejection of claim 1, as asserted by the Examiner.

Appellant respectfully requests reconsideration and withdrawal of the §102 rejection for independent claim 1, as well as claims 2, 4-7 and 43 that depend therefrom.

Claim 20

The Examiner's Supplemental Answer asserts that:

> the applicant admitted that heat is generated when a magnetic field is applied to the Garibaldi-'823 stent formed of patches 120, but argued that the generated heat is **not sufficient** to treat a treatment site of a patient. However, independent claim 20 **does not** specify how much heat is sufficient. Therefore, it is impossible for one of ordinary skill in the art to recognize the difference between the present claimed invention and the Garibaldi-'823 device.

Appellant respectfully traverses. First, Appellant indicated that heat may be generated in pointing out that the Examiner has not presented any evidence to make clear how one skilled in the art would recognize that the "patch 120" should be heated with the electromagnetic field "B" to a temperature sufficiently high to treat a treatment site.

As discussed in Appellant's Appeal Brief and Reply Brief to Examiner's Answer, the Examiner asserted that there was "[i]nherently, a change in an electromagnetic field from a zero value to B value applied to Garibaldi-'823's stent 120 will create some level of heat in stent 120. Therefore, Garibaldi-'823 inherently discloses the claimed invention." Appellant respectfully traverses.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing

descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

Claim 20 recites that the vascular treatment system includes a medical device that heats to a temperature sufficient to treat a treatment site when an electromagnetic field is applied. So, claim 20 provides that the heat from the medical device is sufficient to treat the treatment site. In contrast, the Examiner asserts that it would be inherent in Garibaldi that electromagnetic field "B" passing through "patch 120" generated some level of heat in the device. While some heat may be generated, evidence presented by the Examiner has not made clear how one skilled in the art would recognize that the "patch 120" should be heated with the electromagnetic field "B" to a temperature sufficiently high to treat a treatment site. As such, it would appear that at best Garibaldi might provide a possibility of heating the "patch 120" to a temperature sufficiently high to treat a treatment site, but possibilities are not a sufficient basis for an inherency argument.

Appellant also traverses the assertion that "independent claim 20 **does not** specify how much heat is sufficient and how much heat is insufficient. Therefore, it is impossible for one skilled in the art to recognize the difference between the present claimed invention and the Garibaldi-'821 device." Appellant respectfully submits that this assertion by the Examiner appears to be a new ground for rejection of claim 20. 37 C.F.R. 41.43(a)(2) provides that a supplemental Examiner's answer responding to a reply brief may not include a new ground of rejection. Appellant respectfully believes this is a new ground for rejection because the assertion as to how much heat is sufficient or insufficient has not, to this point, be raised by the Examiner as a basis and/or a reason for rejecting claim 20.

While Appellant's position is that the above assertion is a new ground for rejection, Appellant also provides an argument as to why this new ground of rejection is insufficient to reject claim 20. Appellant respectfully submits that claim

20 recites, in part, that "the implantable device heats to a temperature sufficient to treat the treatment site when the electromagnetic field is applied." One skilled in the art would reasonably understand that temperatures sufficient to treat a treatment site could include those to treat vascular conditions. For example, Appellant's provide an example of such heating to a temperature sufficient to treat a treatment site for restenosis in the specification as originally filed at page 10, line 27 to page 12 line 18. As such, one skilled in the art would understand the amount of heat that would be sufficient to treat the treatment site based on claim 20, and would be able to recognize the difference between the present claimed invention and the Garibaldi-'821 device.

Appellant respectfully requests reconsideration and withdrawal of the §102 rejection for independent claim 20, as well as claims 21-25 and 47 that depend therefrom.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 8, 11, 26 and 29

For claims 8, 11, 26 and 29, the Examiner's Supplemental Answer asserted:

> the applicant (Appellant's Reply Brief, page 16, paragraph 3) argued that Gadolinium is a malleable and ductile material that cannot possess the proper **elastic properties** to provide the function required by hoop 122 of Nitinol, for example, as disclosed by Garibaldi-'823. However, it is well known that a [*sic*] Gadolinium is as elastic as nitinol because they have very similar modulus of elasticity. Indeed, the modulus of Gadolinium is about 75.8 Gpa . . . in comparison with that of Nitinol (about 75Gpa in austenite state or super-elastic state . . .) Notice that in a martensite state, Nitinol is more ductile because the modulus of elasticity of Nitinol is only about 40 Gpa . . . , but still more elastic than lead . . . . (page 4, Examiner's Supplemental Answer).

Appellant respectfully traverses.

Appellant is unsure why a comparison of the elasticity of Nitinol to lead is being made by the Examiner. It is not readily apparent why Nitinol in its martensite

state being more elastic than lead would have lead one skilled in the art to substitute Gadolinium for Nitinol in the hoop 122. Clearly the pure element lead cited by the Examiner would not be used in an implantable medical device.

The Examiner also asserts that "hoop 122 of nitinol" could be replaced with the element gadolinium. Garibaldi discusses the use of the element gadolinium in conjunction with the magnetically controllable embolic material (see col. 13, lines 10-17 and 29-33). However, the element gadolinium is a malleable and ductile metal that does not possess the proper elastic properties to provide the function required by the hoop 122 (i.e., the ability to cause the patch to "open"). In other words, a "hoop 122" made of the element gadolinium, as suggested by the Examiner, once compressed (e.g., bent) or wrapped around a catheter would not have the ability to "open to its normal (preferred round) shape" by itself as required by Garibaldi.

The reason for this is that gadolinium is neither a superelastic material nor is it a "shape memory" metal like Nitinol. As noted by the Examiner, the Modulus of Elasticity (or Young's Modulus (E)) for Gadolinium is approximately 76 GPa. The Modulus of Elasticity for Nitinol, however, has different values based on its crystalline phase (e.g., austenite and martensite). As is known to one skilled in the art, the shape memory effect of Nitinol is the process of restoring an original shape of a plastically deformed sample by heating it. This is a result of a crystalline phase change known as "thermoelastic marensitic transformation." Below the transformation temperature, Nitinol is martensitic having a Young's Modulus of approximately 28 to 41 GPa. In this state, the Nitinol can be deformed from its original shape to be loaded onto, for example, the "catheter 22" of Garibaldi. At the delivery site, the body heat converts the Nitinol to its high strength austenitic condition, with a Young's modulus of approximately 83 GPa, as it transforms back to its original shape. This ability to undergo this transformation is what makes Nitinol desirable in the application proposed in Garibaldi and why gadolinium is not a suitable substitute.

In contrast to Nitinol, Gadolinium is a polycrystalline structure that does not undergo a thermoelastic transformation like Nitinol. So, once gadolinium is

deformed it will not recover its original shape through the application of heat. As illustrated in Garibaldi, the "patch 120" is wound around the "catheter 22" (see Fig. 12B of Garibaldi). Unlike Nitinol, Gadolinium does not possess the property of having two yield stress states (one for its austenite state and one for its martensite state). So, once the Gadolinium is deformed by bending around the "catheter 22", a "hoop 122" of gadolinium cannot return to its original shape through the application of body heat. This is most likely why Garibaldi chooses only Nitinol for this application, as it can undergo this deformation in its martensite state with the ability to recover its original shape upon transformation to the austenite state. As such, one skilled in the art would most likely not have chosen to use Gadolinium in place of Nitinol for "hoop 122" as suggested by the Examiner.

So, modifying Garibaldi as suggested by the Examiner would render the "patch 120" unsatisfactory for its intended purpose. As such, there is no suggestion or motivation to make the proposed modification as asserted by the Examiner.

In addition, as discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claims 1 and 20. As claims 8 and 11 are dependent claims of independent claim 1, and claims 26 and 29 are dependent claims of independent claim 20, the 103 rejection of claims 8, 11, 26 and 29 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejections of claims 8, 11, 26 and 29.

Claim 12

The Examiner maintains the assertion that even though Garibaldi does not disclose FeO (ferrite oxide) or CrO (chromium oxide) as a magnetically susceptible material, these materials are well known magnetically susceptible materials that could be used in place of a gadolinium or a PdNi, "as long as a substitute of a ferrite oxide or a chromium oxide does not destroy the function of the device." Appellant traverses the assertions.

Appellant respectfully submits that this assertion by the Examiner appears to be a new ground for rejection of claim 12. 37 C.F.R. 41.43(a)(2) provides that a

supplemental Examiner's answer responding to a reply brief may not include a new ground of rejection. Appellant respectfully believes this is a new ground for rejection because the assertion that as long as a substitute of a ferrite oxide or a chromium oxide does not destroy the function of the device then the substitution would have been obvious has not, to this point, be raised by the Examiner as a basis and/or a reason for rejecting claim 12.

Appellant respectfully repeats the request for a document in support of this ability to substitute FeO and/or CrO for gadolinium or PdNi. Appellant makes this request based on the fact that gadolinium and PdNi where chosen by Garibaldi based on their Curie temperature (see col. 13, lines 29-31) that are not matched by FeO and/or CrO. As such, one skill in the art would not have reasonably believed that FeO and/or CrO could be substituted for gadolinium or PdNi as easily as is suggested by the Examiner. In other words, there is a specific necessary reason why Garibaldi selects gadolinium and PdNi (i.e., for their Curie temperature) that is not matched by using FeO and/or CrO.

In addition, as discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claim 1. As claim 12 is a dependent claim of independent claim 1 the 103 rejection of claim 12 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejection of claim 12.

Claim 28

Appellant respectfully submits that a proper *prima facie* case of obviousness continues not to have been established for claim 28.

For claim 28, the Examiner's Supplemental Answer asserted:

> Doscher-'904 teaches using a magnetic field as disclosed in US Pat. 6,238,421 to generate heat to a partial coating of a magnetically susceptible material of a stent which is implanted to treat an inner surface of a blood vessel of a patient more effectively (Doscher-'904: col. 10, lines 59-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a Doscher-'904 stent partially coated for an effective treatment of the inner surface of the patient blood vessel.

> Further, Garibaldi-'823 discloses a stent including a magnetically susceptible material implanted in a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a Garibaldi'-823 having a partial coat of a susceptible material so that one can effectively direct the heat source generated by a magnetic field to an inner surface of a blood vessel. (pages 5-6)

The Appellant respectfully traversed these assertions.

Appellant respectfully submits that these assertions by the Examiner appear to be a new ground for rejection of claim 28. 37 C.F.R. 41.43(a)(2) provides that a supplemental Examiner's answer responding to a reply brief may not include a new ground of rejection. Appellant respectfully believes this is a new ground for rejection because the assertion as to the motivation and/or reason why one skilled in the art would have modified Garibaldi and/or Doscher has now only been suggested to the Appellant.

Appellant further submits that one skilled in the art would not have been motivated to provide the magnetically susceptible material on less than the entire core as this would go against Garibaldi's cited purpose of holding the "patch 120" against a vessel wall with a transverse gradient field (col. 8, lines 53-55). Appellant respectfully submits that one skilled in the art would want to maximize this holding force by providing as much of the magnetic material as possible. So coating less than the entire core would run contrary to the understanding of one skilled in the art.

As is known, there are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. As discussed above, the teaching of Garibaldi would not appear to suggest minimizing the amount of magnetic material used on the "patch 120." Also, the nature of the problem addressed in Garibaldi does not appear to warrant a reduction in the amount of magnetic material for the reasons discussed herein. Finally, Garibaldi does not appear to provide an insight into what knowledge one skilled in the art would have motivated and/or provided the desirability to go contrary to the stated goal of applying the "patches 120" to the vessel wall with a magnetic force by reducing the amount of the magnetic material used.

In addition, as discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claim 20. As claim 28 is a dependent claim of independent claim 20 the 103 rejection of claim 28 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejection of claim 28.

Claims 44, 45, 48 and 49

Appellant respectfully submits that a proper *prima facie* case of obviousness has not been established for claims 44, 45, 48 and 49.

For claims 44, 45, 48 and 49, the Examiner asserted:

> Garibaldi-'823 (col. 8, lines 2-15; Fig. 10-12) discloses hoop 122 of nitinol and outer layer/coating having iron particles as a magnetic material. Garibaldi-'823 does not discloses [*sic*] the layer/coating is sintered or painted. However, the manner of making the layer/coating will be given more patentablility in a method claim. (page 6)

Appellant respectfully traverses the assertion that the claims refer to a manner of making a layer/coating. To the contrary, the claims recite a structure for the coating. For example, claims 44 and 48 recite that the coating includes "a sintered coating," (in contrast to reciting "sintering the coating . . .). Similarly, claims 45 and 49 recite that the coating includes "a painted coating," (in contrast to reciting "painting the coating . . .). Appellant respectfully submits that they are unable to find a teaching or suggestion in Garibaldi of either a sintered coating or a painted coating, as recited in claims 44, 45, 48 and 49. As such Garibaldi does not appear to teach or suggest all the elements recited in claims 44, 45, 48 and 49.

In addition, as discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claims 1 and 20. As claims 44 and 45 are dependent claims of independent claim 1, and claims 48 and 49 are dependent claims of independent claim 20, the 103 rejection of claims 44, 45, 48 and 49 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejections of claims 44, 45, 48 and 49.

Claims 42 and 46

As discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claims 1 and 20. As claim 42 is a dependent claim of independent claim 1, and claim 46 is a dependent claim of independent claim 20, the 103 rejection of claims 42 and 46 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejections of claims 42 and 46.

The Examiner is invited to telephone Appellant's attorney, Joseph C. Huebsch, at (612) 236-0122 with regard to this matter.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: **MS APPEAL BRIEF-PATENTS** Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450, on this 17th day of November, 2006.

Sarah L. Reichard
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Nov. 17, 2006
Date:

VIII. CLAIMS APPENDIX

The Claims on Appeal

1. (Previously Presented) A vascular treatment device, comprising:

a stent formed with a magnetically susceptible material having a magnetic susceptibility that decreases within a preselected temperature range.

2. (Original) The vascular treatment device of claim 1, wherein the susceptible material has a Curie temperature in the preselected temperature range.

3. (Canceled)

4. (Previously Presented) The vascular treatment device of claim 1, wherein the stent includes a core, where the susceptible material comprises a coating on a surface of the core.

5. (Original) The vascular treatment device of claim 4, wherein the coating is disposed on an external surface of the core.

6. (Original) The vascular treatment device of claim 4, wherein the coating is disposed on an internal surface of the core.

7. (Original) The vascular treatment device of claim 4, wherein the coating is disposed on both an internal and external surface of the core.

8. (Previously Presented) The vascular treatment device of claim 1, wherein the stent includes a core, where the core is formed of the susceptible material.

9.-10. (Withdrawn)

11. (Original) The vascular treatment device of claim 4, wherein the core comprises a magnetically susceptible material.

12. (Original) The vascular treatment device of claim 1, wherein the susceptible material comprises one of Ferrite Oxide (FEO) and Chromium Oxide (CrO).

13.-19. (Withdrawn)

20. (Original) A vascular treatment system, comprising:

an electromagnetic field generator; and

a medical device deliverable to a treatment site and including a magnetically susceptible material being magnetically susceptible to an electromagnetic field generated by the generator and having a Curie temperature in a preselected temperature range, such that the implantable device heats to a temperature sufficient to treat the treatment site when the electromagnetic field is applied.

21. (Original) The vascular treatment system of claim 20, wherein the medical device comprises;

a stent having a core material.

22. (Original) The vascular treatment system of claim 21, wherein the susceptible material comprises a coating on a surface of the core material.

23. (Original) The vascular treatment system of claim 22, wherein the coating is disposed on an external surface of the core material.

24. (Original) The vascular treatment system of claim 22, wherein the coating is disposed on an internal surface of the core material.

25. (Original) The vascular treatment system of claim 22, wherein the coating is disposed on both an internal and external surface of the core material.

26. (Original) The vascular treatment system of claim 21, wherein the core material is formed of the susceptible material.

27. (Withdrawn)

28. (Original) The vascular treatment system of claim 22, wherein only preselected portions, less than the entire core, are coated with the susceptible material.

29. (Original) The vascular treatment system of claim 22, wherein the core material comprises a magnetically susceptible material.

30.-33. (Withdrawn)

34. - 41. (Canceled)

42. (Previously Presented) The vascular treatment device of claim 1, wherein the coating includes a polymer binder for the magnetically susceptible material.

43. (Previously Presented) The vascular treatment device of claim 1, wherein the core is a metal selected from the group stainless steel, Nitinol, and tantalum.

44. (Previously Presented) The vascular treatment device of claim 1, wherein the coating includes a sintered coating of the magnetically susceptible material on the core.

45. (Previously Presented) The vascular treatment device of claim 1, wherein the coating includes a painted coating of the magnetically susceptible material on the core.

46. (Previously Presented) The vascular treatment device of claim 20, wherein the coating includes a polymer binder for the magnetically susceptible material.

47. (Previously Presented) The vascular treatment device of claim 20, wherein the core is a metal selected from the group stainless steel, Nitinol, and tantalum.

48. (Previously Presented) The vascular treatment device of claim 20, wherein the coating includes a sintered coating of the magnetically susceptible material on the core.

49. (Previously Presented) The vascular treatment device of claim 20, wherein the coating includes a painted coating of the magnetically susceptible material on the core.

IX. EVIDENCE APPENDIX

No evidence is submitted.

X. RELATED PROCEEDINGS APPENDIX

As there are no appeals or interferences known to Appellant's Representatives which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal. There are no copies of decisions rendered by a court or the Board to submit.